REMARKS

Claims 1-24 are currently pending in the present application, with claims 8-24 having been provisionally withdrawn by the Examiner as being directed to a non-elected species. Thus, claims 1-7 are currently under consideration pending the allowance of a generic claim. Claim 1 is an independent claim drawn to a pharmaceutical product with claims 2-7 depending therefrom and adding further limitations. The claims have been amended to better clarify the subject matter contained therein. Applicant submits that no new matter within the meaning of 35 U.S.C. 132 is added by the claim amendments

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being obvious over Jerussi et al. (U.S. Patent No. 6,197,828) in view of Amey et al. (U.S. Patent No. 6,245,350) for the inclusion of tablets into a capsule.

These remarks are presented in the expectation that they place this application in condition for allowance. Accordingly, entry of the remarks is respectfully requested.

Rejection of Claims 1-7 under 35 U.S.C 103(a)

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being obvious over Jerussi et al. (U.S. Patent No. 6,197,828) in view of

Amey et al. (U.S. Patent No. 6,245,350) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Applicant respectfully submits that the references of record, the Jerussi et al. patent and the Amey et al. patent, do not teach or suggest Applicant's inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify

the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

A. The present inventive subject matter

As is indicated above, independent claim 1 is drawn to a pharmaceutical product **comprising** a therapeutically effective amount of a pharmaceutical, at least one compressible material, and at least one lubricating material. The encapsulated product is **in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. The remaining claims depend from claim 1 and add further limitations thereto.

B. The prior art

As has been indicated in the previous responses, the Jerussi et al. patent (U.S. Patent No. 6,197,828) discloses methods of preparing, and compositions comprising, derivatives of (+) venlafaxine. The dosage form may include tablets, caplets, troches, lozenges, dispersions, suspensions, suppositories, ointments, cataplasms, pastes, powders, dressings, creams, plasters, solutions, capsules, soft elastic gelatin capsules, and patches.

Likewise, the Amey et al. patent (U.S. Patent No. 6,245,350) discloses a process for encapsulation of caplets in a capsule and solid dosage forms obtainable by the process. The Amey et al. patent discloses a process for encapsulation of a caplet in a capsule by cold shrinking together capsule parts, which are filled with the caplets.

C. The differences between the claimed subject matter and the prior art

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claim. Claim 1 (and the claims which

depend therefrom) **comprising** a pharmaceutical product **in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**.

Applicant respectfully reiterates that Jerussi et al. and Amey et al. fail to teach or suggest an encapsulated product comprising the novel combinations of ingredients and sizes. This is especially true given the unique nature of the sizes of the claimed products. In support of this position, Applicant respectfully submits herewith comparative test data showing the desired delivery of a pharmaceutical from the claimed caplets in comparison with a larger tablet and a capsule filled with granules.

Applicant prepared an in vitro dissolution test to indicate the importance of the size of the caplets on the desired dissolution profile. In particular, Applicant prepared a composition containing (all percentages herein are given as weight percent) 61.88% venlafaxine Hcl, 16.21% glyceryl behenate, 16.21% microcrystalline cellulose, 4.38% ethyl cellulose, 0.88% magnesium stearate, and 0.88% purified talc. The ingredients were granulated and dried, then coated with a solution containing 5.00% ethyl cellulose, 0.50% triethyl citrate, and 94.50% isopropyl alcohol. The composition was then divided into three portions. A first

portion was loaded (as granules) into a capsule. A second portion was tableted to a size of 11 mm, while the third portion was compressed into caplets having a size of 3 mm. The three products were then tested for their dissolution profile in 0.1N Hcl using paddles at 100 rpm with a volume of 1000 ml. The results of the dissolution are shown in the attached chart.

As can be seen from the chart, Applicant has found that caplets having the claimed size exhibit a more desired release profile, having a zero order. Surprisingly, the larger tablets and the capsules containing the granules exhibited release profiles that were very similar, and were not of zero order. Thus, the data shows that the smaller size of the caplets provides greater control over the release of the active ingredient.

With the above as a basis, Applicant again respectfully reiterates that the Jerussi et al. patent **fails to disclose the dosage form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. This important limitation is found in independent claim 1, and thus also in the dependent claim, and since the Jerussi et al. patent **fails to disclose this limitation**, Applicant submits that the Jerussi et al. patent **fails to render obvious claims 1-7**, since there is no motivation to modify the

reference in an attempt to achieve the presently claimed inventive subject matter.

The Examiner argues in the Office Action on Page 3 that "...there is nothing in the Jerussi reference or the Amey reference that materially affect the basic and novel characteristic(s) of the claimed invention." Applicant respectfully disagrees with this assertion. As is indicated above and in the attached data, the unique properties of the presently claimed invention are a result from the size of the dosing unit. Neither reference discloses the small size for the dosing unit, and therefore, the references fail to disclose the limitation that provides the uniqueness of the presently claimed inventive subject matter. The size imparts the unique features of the invention, and neither reference discusses the size of the dosing unit.

In particular, the Examiner relies on the Amey et al. patent for the proposition that the caplets may be encapsulated in a capsule. However, Applicant respectfully submits that the Amey et al. patent **fails to cure the deficiency** of the Jerussi et al. patent. In other words, Applicant respectfully submits that the Amey et al. patent also **does not disclose** the limitation regarding the size of the caplets as claimed in the present claims under consideration.

Thus, assuming *arguendo*, that the Jerussi et al. patent and the Amey et al. patents were combined in an attempt to achieve the presently claimed subject matter, Applicant respectfully submits that the combination of the patents **would still not disclose** all of the limitations of the present claims. **In particular, the combination of the patents would not include the limitation regarding the size of the caplets.**

Since this deficiency would still be present, Applicant respectfully submits that the Examiner has failed to prove a *prima facie* case of obviousness, which requires that the prior art references teach or suggest all of the claimed limitations. It is clear that the prior art references cited by the Examiner fail to accomplish this, and thus the claims are not obvious over the references. Applicant, therefore, respectfully request reconsideration and withdrawal of the alternative obviousness rejection.

Accordingly, Applicant respectfully submits that the present inventive subject matter, as claimed in claims 1-7, is not rendered obvious by the combination of the Jerussi et al. patent with the Amey et al. patent. Applicant request reconsideration and withdrawal of this rejection.

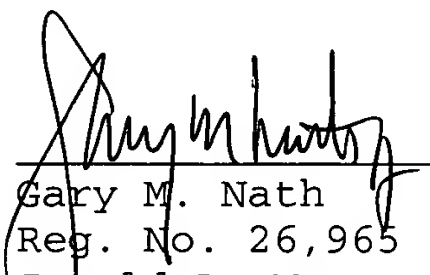
CONCLUSION

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

NATH & ASSOCIATES



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